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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/458,579

12/09/1999

MILES B. BRENNAN

3718-6

9014

7590

09/25/2002

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/25/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,579

Applicant(s)

BRENNAN ET AL.

Examiner

Jegatheesan Seharaseyon

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 15, 16, 19, 20 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 22-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 18.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment and request for reconsideration filed on 7/01/02 in Paper No: 20. Claims 6-9, 17-18 and 21 have been cancelled. Claims 19, 22 and 26-28 are amended. Claims 1-5, 15, 16, 19, 20 and 22-38 are pending.

Therefore, this Office action includes them in 35 U.S.C. 112, first paragraph rejection.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph, maintained

3. Rejection of claims 19-20 and 22-29 under 35 U.S.C. 112, first paragraph for failing to satisfy the written description requirement is maintained. An oversight of the Office resulted in claims 19-20 not being included in the 35 U.S.C. 112, first paragraph rejections in the previous Office action. Applicant's arguments filed on 7/01/02 in reference to claims 22-29 have been fully considered but are not persuasive. Applicant states that melanocortin receptors MC1-R through MC5-R are described in the specification. This is not in dispute. However, it appears that the Applicant, at the time the invention was made, recognized only MC2-R and /or MC5-R to be the peripheral receptors with the ability to stimulate lipolysis and/or to inhibit fatty acid uptake by adipocytes, and in particular, to control obesity (see pages: 65-68; page: 76, lines 23-25). There is no disclosure that any other melanocortin receptor was a peripheral receptor with a role in regulating body weight and energy homeostasis. Thus, the lack of written description rejection is maintained. Claim 20 is rejected insofar as it depends on claim 19.

4. Rejection of claims 19-20 and 22-29 under 35 U.S.C. 112, first paragraph for failing to satisfy the scope of enablement requirement is maintained. As indicated above in paragraph 3, an oversight of the Office resulted in claims 19-20 not being included in the 35 U.S.C. 112, first paragraph rejections in the previous Office action. The Office appreciates Applicant's clarification of the claim numbers. The rejection was indeed for claims 22-29 and not claim 17 as stated in the previous action. Applicant's arguments filed on 7/01/02 in reference to claims 22-29 have been fully considered but are not persuasive. Applicant states that the melanocortin receptor genes and proteins were well known. Although, the specification discloses melanocortin receptors MC1-R through MC5-R, it appears that the Applicant recognized only MC2-R and /or MC5-R to be the peripheral receptors with the ability to stimulate lipolysis and/or to inhibit fatty acid uptake by adipocytes, and in particular, to control obesity (see pages: 65-68; page: 76, lines 23-25). There is no correlation or suggestion of other melanocortin receptors being involved in the regulation of body weight and energy homeostasis. Despite the knowledge in the art of the other melanocortin receptors, the specification fails to provide any guidance to the use of MC1-R and MC3-R in the regulation of body weight and energy homeostasis. Therefore the amount of experimentation required to make and/or use the full scope of claimed receptors would require undue trial and error experimentation. Given the breadth of claims 19-20 and 22-29 in light of the unpredictability of the art as determined by the lack of working examples and shown by

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the prior art of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the full scope of the claimed invention. Claim 20 is rejected insofar as it depends on claim 19.

Claim Rejections - 35 USC § 102, withdrawn

5. Applicant's arguments and canceling of claims 6-9, 17, 18 and 21 have obviated the rejection under 35 USC 102, as being anticipated by Boston et al.

New Ground of Rejections

6. The following is a new ground of rejection necessitated by applicant's addition of claims 30-38.

Claim Rejections - 35 USC § 112

7. Claims 30-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.* Claims 30 and 35 are rejected for failing to satisfy the written description requirement for the same reasons as indicated above in paragraph 3. Claims 31-34 and 36-38 are rejected insofar as they depend on claims 30 and 35.

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8. Claims 30-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 30 and 35 are rejected for failing to satisfy the scope of enablement requirement as indicated above in paragraph 4. Claims 31-34 and 36-38 are rejected insofar as they depend on claims 30 and 35.

9. Claims 1-5, 15 and 16 are allowed. Claims 19, 20 and 22-38 are rejected. However, claims that are drawn to MC2-R and MC5-R receptors for the regulation of body weight and energy homeostasis will be allowable over prior art.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

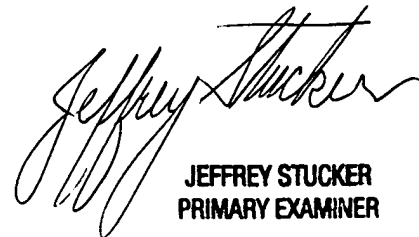
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
September 24, 2002



JEFFREY STUCKER
PRIMARY EXAMINER